

**REMARKS**

**The Amendment**

In the specification, the generic names of the trademarks are added. The generic names are supported by the Trademark Electronic Search System.

The amendments in Claim 32 are supported, for example, by page 5, lines 14-15; page 6, lines 13-16 and 29-30, and original Claims 34-36.

The amendments in Claim 45 are supported, for example, by page 5, lines 15-18; page 32, lines 24-27.

No new matter is added in any of the above amendments. The Examiner is requested to enter the amendment and reconsider the application.

**The Response**

**Oath/Declaration**

The Examiner states that the Inventor's Declaration is defective because it contains an improper foreign priority claim.

Applicants are submitting herewith a new Declaration in which the priorities are properly claimed.

**Title**

The Examiner states that the title of the invention is not descriptive of the subject matter of the elected invention.

Applicants have amended the title to "METHODS OF DIAGNOSING BREAST CANCER" as suggested by the Examiner.

**Objection to Disclosure**

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicants have deleted the embedded hyperlink and/or other form of browser-executable code.

The Examiner has noted the use of the trademarks GeneChip™, Teflon™, Oligotex™, and RNeasy® in this application. Applicants have amended the application to insert the generic name of each trademark.

### **Drawings**

Applicants are submitting herewith corrected Formal Drawings, Figures 1-3, in response to the Draftperson's Notice.

### **35 U.S.C. §112, First Paragraph Rejection**

Claims 32-49 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for methods of diagnosing breast cancer in a human in which increased expression of SEQ ID NO: 1 or SEQ ID NO: 4 or of another nucleic acid encoding the amino acid sequence of SEQ ID NO: 5, as compared to levels for these sequences in a normal human breast tissue sample, are detected in a breast tissue sample of a human patient, does not allegedly provide enablement for methods of diagnosing or determining the prognosis for breast cancer in any type of "individual" using any type of "sample" in which the expression of any gene "at least 75% identical to SEQ ID NO: 1 or SEQ ID NO: 4" is determined.

Claims 34-36, 38-40, 42, and 47 are canceled. The rejection of the remaining claims is overcome in view of the amendments.

Applicants have amended Claim 32 and 45 to recite determining the expression of a gene encoding SEQ ID NO: 5 (the amino acid sequence of BCR4) and a breast tissue sample.

Applicants have further amended Claim 32 and 45 to recite a human individual.

Therefore, the §112, first paragraph rejection of Claims 32, 33, 37, 41, 43-46 and 48-49 should be withdrawn.

### **35 U.S.C. §112, Second Paragraph Rejections**

Claims 32-49 are rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claims 34-36, 38-40, 42, and 47 are canceled. The rejection of the remaining claims is overcome in view of the amendments.

Claims 32-49 are allegedly indefinite over the recitation of the language “determining the expression of a gene at least 75% identical to the sequence disclosed in Figure 1 or Figure 2” in claims 32 and 45. Claims 32 and 45 are amended to recite determining the expression of a gene encoding SEQ ID NO: 5.

Claims 32-44 are allegedly indefinite over the recitation of the limitation “the expression of said gene(s)” in claim 32. Claim 32 is amended to recite the expression of said gene.

Claims 32-44 are allegedly indefinite over the recitation of the language “said comparison is used to diagnose breast cancer.” Claim 32 is amended to recite whereby the overexpression of said gene in the first breast tissue sample indicates breast cancer in said human individual.

Claim 41 is allegedly indefinite over the recitation of the phrase “said gene is the gene disclosed in Figure 1 or Figure 2.” Claim 41 is amended to recite said gene comprises a nucleic acid of SEQ ID NO: 4.

Claims 42 and 47 are allegedly indefinite over the recitation of the limitation “said gene encodes BCR4.” Claims 42 and 47 are canceled.

Claims 45-49 are allegedly indefinite over the recitation of the language “wherein the expression of the gene is used to determine the prognosis of the individual” in claim 45. Claim 45 is amended to recite that wherein the expression of the gene at different cellular states is used to determine the prognosis of the individual.

Claim 46 is allegedly indefinite over the recitation of the phrase “said gene is the sequence disclosed in Figure 1 or Figure 2.” Claim 46 is amended to recite said gene comprises a nucleic acid sequence of SEQ ID NO: 4.

Therefore, the §112, second paragraph rejection of Claims 32, 33, 37, 41, 43-46 and 48-49 should be withdrawn.

### **35 USC §102(e) Rejection**

Claims 32-40 and 43 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Goddard, *et al.* (WO 01/55178 A2). Claims 34-36 and 38-40 are canceled. The rejection to the remaining claims is traversed in parts and overcome in parts in view of the amendments.

Goddard, *et al.* disclose LIV-1 gene sequences. The LIV-1 sequence has some homology, but is not identical to the gene encoding SEQ ID NO: 5. At page 5, lines 14-20, the instant specification describes that the amino acid sequence of SEQ ID NO:5 (BCR4) is similar to the published sequence for human LIV-1, but different by the sequences indicated with boxes. The sequence HDHSH (indicated with a box) of BCR4 results from the additional 18 base sequence of the mRNA. The sequence at the carboxy terminus (also indicated with a box) differs from the published sequence for LIV-1 polypeptide, due to a shift in the reading frame resulting from the two additional thymine residues of BCR4 not found in the published LIV-1 nucleic acid sequence.

Because Goddard, *et al.* do not disclose a sequence encoding SEQ IN NO: 5, the §102(e) rejection of Claims 32, 33, 37, and 43 should be withdrawn.

### **35 USC §103(a) Rejection**

Claims 45 and 48 are rejected under 35 U.S.C. §103(a) as being allegedly unpatentable over Goddard, *et al.* (WO 01/55718 A2) in view of Taylor, *et al.* (Brit. J. Cancer 80:24 (1999)). The rejection is traversed in parts and overcome in view of the amendments.


For the same reasons as described above, the primary reference of Goddard, *et al.* do not disclose a sequence encoding SEQ ID NO: 5. The addition of Taylor, *et al.* does not cure the deficiency. Therefore, the §103(a) rejection of Claim 45 and 48 should be withdrawn.

### **CONCLUSION**

Applicants believe that the application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is encouraged to call the undersigned at (650) 463-8109.

Respectfully submitted,

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